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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,699	06/19/2002	Theodore E. Cadell	270.63USWO	4601
23552	7590	07/12/2004	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			POLYZOS, FAYE S	
			ART UNIT	PAPER NUMBER
			2878	

DATE MAILED: 07/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/049,699	CADELL, THEODORE E.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Faye Polyzos	2878	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 7-11 is/are rejected.
- 7) ☒ Claim(s) 2-6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/15/2002</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### Comment on Submissions

1. This communication is responsive to submissions of February 15, 2002.

### **Claim Rejections - 35 USC § 103**

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Rosenthal (US 5,576,544)* in view of *Small (Strategies for Coupling Digital Filtering with Partial Least-Squares Regression: Application to the Determination of Glucose in Plasma by Fourier Transform Near-Infrared Spectroscopy, 1993)*.

Regarding claim 1, *Rosenthal* discloses (Fig. 1-6) a method of calibrating a spectroscopic device for providing a non-invasive measurement of an analyte level in a sample, comprising: providing a plurality of calibration algorithms (col. 2, lines 63-65); taking a set of non-invasive measurements on a sample with a spectroscopic device (col. 3, lines 36-38); calculating a predicted set of analyte levels for each of the calibration algorithms in response to the set of non-invasive measurements (col. 5, lines 36-39), where each of the predicted sets of analyte levels being characterized by calibration constants and a standard error of prediction (col. 6, lines 7-9) and selecting an appropriate calibration algorithm by using a suitability score based on the a

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calibration constant; and the standard error by prediction for each of the predicted sets of analyte levels (col. 6)

*Rosenthal* discloses analyte levels are characterized by calibration constants such as  $R^2$  but does not specifically disclose calibration constants comprising slope or variable range in determining a predicted set of analyte levels.

*Small* discloses calculating a predicted set of analyte levels for each of the calibration algorithms in response to the set of non-invasive measurements where each of the predicted sets of analyte levels may be characterized by future constant including variability range, slope,  $R^2$  and standard error of prediction (See Fig. 4, Table I and III, p.3282, col. Left). *Small* further discloses, selecting an appropriate calibration algorithm by using a suitability score based on variability range, the slope, the  $R^2$  and the standard error of prediction for each of the predicted sets of analyte levels (See Fig. 4, p.3282, col. left). *Small* teaches the calibration and prediction results indicate that the spectral range is a key variable in the calibration model development. Therefore, it would have been obvious to modify the method discussed by *Rosenthal* so as to select an appropriate calibration algorithm using additional constant and suitability score in view of teaching by *Small* that selecting the appropriate spectral range is a key variable in calibration model development.

Regarding claim 7, *Rosenthal* further discloses a plurality of calibration algorithms are generated by the steps of: compiling non-invasive and corresponding reference data sets of measurements of analyte levels for each of a number of samples (col. 3, lines 60-67 and col. 4, lines 9-18); combining data sets that are suitable for

calibration into a plurality of groups depending on whether correlation of the combined data sets meet predetermined criteria (col. 4, lines 26-29) and generating a calibration algorithm for each of the groups of data sets (col. 4, lines 17-25). Although *Rosenthal* does not specifically disclose a step of rejecting data sets that are not suitable, *Rosenthal* does support selecting only those data sets that have certain significant differences from each other (col. 4, lines 25-29), such selection obviously, if not indifferently, suggests that data sets without certain significant differences are rejected.

Regarding claim 8, *Rosenthal* discloses the predetermined criteria include minimizing correlations of combined data sets in a particular group with parameters other than the analyte and maximizing the correlation between data sets in a particular group (col. 3, lines 60-67 and col. 4, lines 1-5).

Regarding claim 9, *Rosenthal* discloses the steps are performed by statistical analysis (col. 4, lines 42-55). Although *Rosenthal* does not disclose the particular type of statistical analysis, those skilled in the art appreciate that a variety of functionally equivalent types of statistical analysis are well known in the art including PLS (See Price at col. 13, lines 8-9). *Small* further discloses PLS regression is one of the most widely used strategies for processing spectral data and building a calibration model for predicting analyte concentrations (p.3281, col. Right). Therefore it would have been obvious to a person of ordinary skill in the art to modify the method suggested by *Rosenthal* so as to perform a PLS statistical analysis, disclosed by *Small*, to provide good linear approximation by removing redundant information.

Regarding claim 10, *Rosenthal* discloses steps generated in compiling, combining and generating calibration algorithms are performed on a computer associated with a spectroscopic device (col. 4, lines 55-62).

Regarding claim 11, *Rosenthal* discloses the sample is an individual patient, the spectroscopic device is a near-infrared spectrophotometer, and the analyte is glucose (col. 3, lines 37-50).

***Allowable Subject Matter***

4. Claims 2-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The following is a statement of reasons for the indication of allowable subject matter:

Regarding dependent claim 2, the prior art does not disclose or fairly suggest a method comprising of the selection of a predicted set of analyte level within an upper and lower limit of range and slope to calculate a suitability score as the appropriate calibration algorithm.

The examiner notes that while it is known in the art to calculate a predicted set of analyte levels based on range, slope and  $R^2$  for multiple calibration algorithms (See *Rosenthal* US 5,576,544 col. 5, lines 65-67 and col. 6, lines 1-24), the prior art does not fairly suggest a method comprising the selection of a predicted set of analyte levels based on a range or slope limit where if no predicted sets are selected an upper or lower error limit is concerned and no calibration algorithm may be appropriate.

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6. Claims 3-6 are allowable based on their dependency to claim 2.

**Conclusion**


7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Faye Polyzos whose telephone number is 571-272-2447. The examiner can normally be reached on 7:30 - 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Porta can be reached on 571-272-2444. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FP



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